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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte TOSHIMITSU ISHIKAWA, NOBUYUKI WADA, FUTAO KAWAGUCHI, and KOJI KAJIMA

Appeal 2007-3909
Application 09/393,168
Technology Center 1600

Decided: February 5, 2008

Before ERIC GRIMES, LORA M. GREEN, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a soft capsule encapsulating a medicinal liquid. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

Conventionally, a "medicinal liquid which is an ingredient or material encapsulated in a soft capsule is constituted of a first medicinal liquid

ingredient of a fat and oil material and a second medicinal liquid ingredient obtained by adding an effective component . . . to a fat and oil material to prepare a mixture and stabilizing the mixture with a suitable emulsifier. Then, the medicinal liquid thus obtained is charged or encapsulated in a soft encapsulating material" (Specification 1).

The Specification teaches that "the soft capsule manufactured by the conventional procedure causes much time to be required for preparation of the medicinal liquid or stock solution, leading to a deterioration in both workability and productivity and an increase in production cost. Also, it tends to cause excessive intake of calorie because of containing a relative large amount of fats and oils" (*id.* at 1-2).

The Specification discloses a soft capsule "which is completely free of such fats and oils and emulsifier," but instead "contains a dietary fiber in an amount of 5 to 90% by weight … of a medicinal liquid of the soft capsule" (*id.* at 2).

DISCUSSION

1. CLAIMS

Claims 1-22 are pending and on appeal. Claims 2-22 have not been argued separately and therefore stand or fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii). Claim 1 is representative and reads as follows:

Claim 1: A soft capsule encapsulating a medicinal liquid comprising a dietary fiber in an amount of 5 to 90% by weight based on a whole composition of the medicinal liquid;

wherein said medicinal liquid is in the form of a suspension which is homogenized and the dietary fiber facilitates suspension of components of the medicinal liquid and stabilizes the suspension.

The phrase "a suspension which is homogenized" is not defined in the Specification. "[A]s an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997). The Specification describes an example in which homogenization is accomplished using a high-speed agitator (Specification 8), but we do not limit the claims to the specific examples. We thus interpret "a suspension which is homogenized" to include suspensions that are homogenized by any process, including low-shear agitation and high-shear agitation.

2. OBVIOUSNESS

Claims 1-22 stand rejected under 35 U.S.C. § 103 as obvious in view of Miskel[1] and Tanner.[2]

The Examiner relies on Miskel as disclosing a soft capsule comprising a dietary fiber (pectin) and other components (e.g., diphenhydramine, vitamin E, or sodium saccharine) (Answer 3). The Examiner finds that Miskel does not disclose a "homogeneous mixture of the medicinal liquid in the soft capsule" (*id.*). The Examiner relies on Tanner as disclosing "fill compositions for soft gel capsules … comprising an active agent dissolved or suspended in a carrier liquid" and the "homogenization of actives and solubilizing agents" (*id.*). The Examiner concludes that the cited references

[1] Miskel et al., US 3,851,051, Nov. 26, 1974.
[2] Tanner et al., US 5,569,466, Oct. 29, 1996.

would have made obvious the capsule of claim 1 to a person of ordinary skill in the art (*id.* at 4).

We conclude that the Examiner has set forth a prima facie case that claim 1 would have been obvious to the ordinary artisan. Miskel discloses soft gelatin capsules containing "a macromolecular gel-lattice matrix … which contains from 30-50% of an aqueous solution or suspension of a chemical, medicinal, or pharmaceutical compound" (Miskel, col. 3, l. 71 to col. 4, l. 1). The gel-lattice matrix is made of "macromolecular compounds which are water-soluble or form colloidal hydrates," such as pectin (*id.* at col. 5, ll. 24-36). Miskel's Examples 1, 43, and 50 contain pectin in amounts of 7.9%, 20%, and 33.2% by weight of the "matrix components" (i.e., medicinal liquid), respectively.[3]

Miskel discloses that "the gel-lattice vehicle is fluid at a temperature of from 30-40° C, and is filled into soft gelatin capsules" (*id.* at col. 3, ll. 71 thru. col. 4, ll. 3). "Upon cooling and drying, the gel lattice vehicle sets to a rigid gel system containing as much as 15-20% water" (*id.* at col. 4, ll. 4-6). Miskel also discloses that the "macromolecular polymer is added to water, which may be heated" and the "mixture is then agitated with low shear agitation to minimize any reduction in the molecular weight of the macromolecular polymers" (*id.* at col. 5, ll. 44-49).

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[3] The capsules in Miskel's Example 1 contain 0.0230 g of pectin in 0.2917 g of total matrix components (Miskel, col. 6, ll. 59-63); thus, 7.9% of the matrix components are pectin. The capsules in Miskel's Example 43 contain 0.1 g of pectin in 0.498 g of total matrix components (Miskel, col. 19, ll. 5-12); thus, 20% of the matrix components are pectin. The capsules in Miskel's Example 50 contain 285.3 mg of pectin in 860 mg of total matrix components (Miskel, col. 20, ll. 69-75); thus, 33.2% of the matrix components are pectin.

We agree with the Examiner that the product of claim 1 would have been prima facie obvious to one of skill in the art based on the teachings of Miskel and Tanner. As set forth above, Miskel discloses the use of pectin (i.e., dietary fiber) in the claimed amounts, as part of a medicinal liquid contained in a soft capsule. Miskel also discloses that the medicinal liquid may contain a suspension of a medicinal compound. A composition containing a medicinal compound in the form of a suspension and a dietary fiber that is water soluble or a colloidal hydrate would reasonably appear to be in the form of a suspension, as recited in claim 1.

Miskel's composition is mixed with low shear agitation prior to the filling of the capsules and thus one skilled in the art would expect that the medicinal liquid that is poured into the capsules is homogenized. Since the instant Specification discloses that "a water-soluble dietary fiber" can be used in the claimed capsules (Spec. 3: 28-30), and the dietary fiber used in Miskel is "water-soluble or form[s] colloidal hydrates" (Miskel, col. 5, ll. 27-28), it is also reasonable to conclude that the dietary fiber in Miskel's capsules "facilitates suspension of components of the medicinal liquid and stabilizes the suspension," as is instantly claimed. The disclosure of Tanner is cumulative, but we note that Tanner also discloses that carrier compounds and medicinal suspensions contained therein are homogenized prior to the filling of capsules (Tanner, col. 4, ll. 65-67).

Appellants argue that Miskel discloses that "the macromolecular gel-lattice matrix is a rigid gel system which sets upon cooling and/or drying," (App. Br. 3) and that "[i]f the contents of the soft gel capsule of Miskel … were homogenized as suggested by the Examiner, the result would be to

destroy the rigid gel system, i.e. matrix, which represents the inventive concept of Miskel" (*id.* at 5).

We are not persuaded by this argument. The Examiner has made clear that the aspect of Miskel that makes obvious the instant claims is "the Miskel composition before cooling and or drying, that is, before … a rigid gel may be formed" (Answer 4). We agree. As discussed above, Miskel's dietary fiber-containing medicinal suspension is homogenized prior to filling of the capsules. Miskel's capsules, after they have been filled and before the matrix has set, reasonably appear to comprise a homogenized medicinal liquid, comprising a dietary fiber, in the form of a suspension.

Appellants further argue that "in accordance with the present invention, the medicinal liquid is a homogenized suspension containing both the dietary fiber and the material of limited oil-solubility (e.g. medicament)" and that this is "in contrast to Miskel … in which the dietary fiber is not in a homogenized suspension with the aqueous solution or suspension of the medicament, but rather, the dietary fiber is part of a rigid gel system which forms a matrix for the aqueous solution or suspension of the medicament" (App. Br. 4).

We are not persuaded by this argument. Claim 1 does not require that the dietary fiber is in suspended form in the medicinal liquid but merely requires that the overall "medicinal liquid is in the form of a suspension". We find that Miskel suggests a medicinal liquid, particularly the liquid fill in the capsules when first formed, that comprises dietary fiber that is water soluble or in the form of a colloid. The medicinal liquid is reasonably considered to be "in the form of a suspension" because Miskel states that the

active ingredient may be in the form of a suspension. "Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification or prosecution history when those sources expressly disclaim the broader definition." *In re Bigio*, 381 F.3d 1320, 1325 (Fed Cir. 2004). Thus, it would be improper to limit claim 1 to a medicinal liquid wherein the dietary fiber is suspended in the medicinal liquid.

SUMMARY

The Examiner's rejection is supported by the preponderance of the evidence of record. We therefore affirm the rejection of claims 1-22 under 35 U.S.C. § 103.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

Ssc:

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